



OCT 7 1999

**. NADA 141-151**

Tracy D. Rockney  
Manager, Regulatory Affairs  
Pfizer Inc., Animal Health Group  
812 Springdale Drive  
Exton, PA 19341-2803

Dear Ms. Rockney:

We refer to your Drug Experience Report dated July 16, 1999, for Zeniquin™ (marbofloxacin) tablets, NADA 141-151. The submission included the Zeniquin™ veterinary advertisement, coded "ZEN0799003." We find this advertisement to be in violation of the FDA advertising regulations.

The advertisement contains a pink balloon with the statement "Hey, *Pseudomonas aeruginosa*\*. You want a piece of me?" The text of the advertisement, in part, says "...Against tough infections commonly associated with *Escherichia coli*, *Pseudomonas aeruginosa*\* and *Staphylococcus intermedius*, greater intensity of exposure may result in high efficacy..." The asterisk indicates *in vitro* activity, which is not consistent with the approved labeling. *In vitro* data used in a way that suggests that it has clinical significance when in fact no clinical significance has been demonstrated is false or misleading [21 CFR § 202.1(e)(6)(vii)].

We ask that you stop making such false and misleading statements in the advertisements and any other similar promotional materials in the future. Please inform us of your intentions within 30 days of receipt of this letter. If you have any questions; you may contact us at (301) 827-6639.

Sincerely yours,

Vitolis Vengris, D.V.M., Ph.D.  
Marketed Product Scientific and  
Regulatory Review, Team 1, HFV-214  
Division of Surveillance  
Center for Veterinary Medicine